OCT - 4 2000

K001460

J.1 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:_____

Contact:	Joan M. Ward Sr. Regulatory Affairs Specialist bioMérieux, Inc. 1022 Hingham St. Rockland MA 02370 781-871-4442 x 162
Submitter:	Janet Connolly bioMérieux, Inc. 1022 Hingham St. Rockland MA 02370 781-871-4442
Date:	May, 2000
Device Trade/Proprietary Name:	VIDAS HPY IgG (HPY) Assay
Common or Usual Name:	Enzyme-linked Fluorescent Immunoassay (ELFA) for the qualitative detection of IgG antibodies to ***Helicobacter pylori***.
Classification Name:	21 CFR 866.3110, *Campylobacter pylori* serological reagents.
Predicate Device:	Meridian Diagnostics Premier H. pylori assay

Device Description:

The VIDAS HPY assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated VIDAS® instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are in the sealed HPY Reagent Strips. After preliminary wash and sample dilution steps, the sample is cycled in and out of the SPR for a specified length of time. IgG antibodies to *H. pylori* present in the specimen will bind to the *H. pylori* antigen coating the interior of the SPR. Unbound sample components are washed away. Anti-human IgG antibodies conjugated with alkaline phosphatase are cycled in and out of the SPR and will attach to any human IgG bound to the SPR wall. A final wash step removes unbound anti-human antibody conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is introduced into the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument. When the VIDAS HPY assay is completed, the results are analyzed automatically by the computer, a test value is generated, and a report is printed for each sample.

J.1 510(k) Summary (continued)

Intended Use:
The VIDAS *H. pylori* IgG (HPY) assay is intended for use with a VIDAS® (Vitek ImmunoDiagnostic Assay System) instrument as an automated qualitative enzyme-linked fluorescent immunoassay (ELFA) for the detection of IgG antibodies to *Helicobacter pylori* in human serum or plasma (EDTA). The VIDAS HPY assay is intended as an aid in diagnosis of *H. pylori* infection in an adult symptomatic population.

Summary/Comparison of Technological Characteristics

The VIDAS HPY assay is substantially equivalent to the Meridian Premier *H. pylori* assay.

Major Similarities Include:
1. Both tests are qualitative enzyme immunoassays, which detect the presence of circulating IgG immunoglobulin to H. pylori in human serum or plasma.
2. Both tests are intended for the use as an aid in the diagnosis of H. pylori infection.

Major Differences Include:
1. The VIDAS H. pylori IgG assay is a fully automated enzyme-linked fluorescent immunoassay (ELFA) which uses sealed Reagent Strips. All reagents necessary to perform the VIDAS H. pylori IgG assay are contained in the reagent strip. Meridian Premier H. pylori assay requires reagent preparation and separate addition of these reagents to the assay system.
2. The VIDAS H. pylori IgG assay uses a Solid Phase Receptacle (SPR) to capture H. pylori antigen. The Meridian Premier uses a 96 plastic microtiter plate for capture.
3. The VIDAS H. pylori IgG assay results can be obtained in approximately 35 minutes. The Meridian Premier H. pylori assay test requires approximately 1 hour.

Synopsis of Performance Testing

Nonclinical Testing:
1. Analytical specificity: In one study, a total of 27 organisms were tested and no analytical specificity problems in the VIDAS HPY assay were found.
2. Precision: Within-run precision calculations as described by NCCLS EP5-A yielded a combined % CV ranging from 2.6 % to 6.1 % over the reportable range of the assay. Total precision calculations as described by NCCLS EP5-A yielded % CV ranging from 2.3% to 17.57 % over the reportable range of the assay.
3. Interference: Interference was not linked to the presence of hemoglobin, bilirubin, or lipemia when analyzing spiked specimens. However, the use of a

hemolyzed, icteric or lipemic specimen is not recommended. If possible, collect a new specimen.

Clinical Testing:

1. Percent Agreement and Concordance (relative to the predicate device): Two hundred and forty seven serum specimens were tested using the using the VIDAS HPY assay and the Meridian Premier H. pylori IgG assay. After re-testing of initial VIDAS equivocal samples (as directed in the package insert), there were 2 VIDAS equivocal results. For the remaining 245 specimens, the VIDAS HPY assay demonstrated a Percent Positive Agreement of 98.3%, Percent Negative Agreement of 91.2% and 94.7% Concordance of results.

These results support a determination of substantial equivalence. When the VIDAS HPY assay is used as instructed in the package insert, the above statements are true. The package insert should always be consulted along with a VIDAS Operator's Manual to ensure that the assay is being performed properly. For additional information, references are listed in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 4 2000

Ms. Joan Ward
Regulatory Affairs Specialist
bioMerieux, Inc.
1022 Hingham Street
Rockland, Massachusetts 02370-1052

Re: K001460
Trade Name: VIDAS H. pylori IgG (HPY) Assay
Regulatory Class: I
Product Code: LYR
Dated: August 14, 2000
Received: August 14, 2000

Dear Ms. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001460/S1

Device Name: VIDAS H. pylori IgG (HPY) Assay

Indications for Use:

The VIDAS *H. pylori* IgG (HPY) assay is intended for use with a VIDAS® (Vitek ImmunoDiagnostic Assay System) instrument as an automated qualitative enzyme-linked fluorescent immunoassay (ELFA) for the detection of IgG antibodies *to Helicobacter pylori* in human serum or plasma (EDTA). The VIDAS HPY assay is intended as an aid in diagnosis of *H. pylori* infection in an adult symptomatic population.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ~~ANOTHER~~ PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001460/S1

Prescription Use X **OR** **Over-the-Counter Use** _____